



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

0341 5 APR 11 P2:07

Docket Nos. 03E-0405 and 03E-0452

Re: Neutersol

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

APR 18 2005

Dear Director Dudas:

This is in regard to the patent term extension applications for U.S. Patent Nos. 5,070,808 and 4,937,234 filed by Technology Transfer, Inc. under 35 U.S.C. § 156. The patents claim Neutersol (zinc gluconate), NADA 141-217.

In the July 7, 2004, issue of the Federal Register (69 Fed. Reg. 40944), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before January 3, 2005, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Grace J. Fishel
Suite 220
11970 Borman Drive
St. Louis, MO 63146

03E-0405

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